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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/211,755	12/15/1998	KENNETH A. JONES	54002-D/JPW/	9496

7590 12/17/2003

JOHN P WHITE
 COOPER & DUNHAM
 1185 AVENUE OF THE AMERICAS
 NEW YORK, NY 10036

EXAMINER

BRANNOCK, MICHAEL T

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 12/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/211,755

Applicant(s)

JONES ET AL.

Examiner

Michael Brannock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 208,210,213,214,221-225,228,230,231,233-239 and 250 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 233 and 234 is/are allowed.
- 6) ☐ Claim(s) 208,210,213,221-225,228,230,231,235-239 and 250 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 041103.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Maintained Rejections:

Claims 208, 210, 213, 214, 221-225, 228, 230, 231, 235-239 and 250 stand rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No: 6518399, as set forth previously.

U.S. Patent No: 6518399 disclose assays for agonists of a GABA_BR1/R2 receptor (e.g. col 14), wherein the GABA_BR1 polypeptide is either the rat GABA_BR1a or GABA_BR1b polypeptide (e.g. col 2), each of which is 100% identical to the instant SEQ ID NO: 56 and 55, respectively, and wherein the GABA_BR2 polypeptide is the human GABA_BR2 (e.g. col 4) that is 100% identical to the instant SEQ ID NO: 47. Assays are also disclosed wherein the activity is measured via changes in cAMP, GTP S incorporation, or GIRK1 and GIRK4-evoked changes in current, see cols 5 and 6. The use of the human GABA_BR2 polypeptide in such assays is fully supported in prior US application 60/103,670, filed October 9, 1998.

Initially, Applicant speculates that U.S. Patent No: 6518399 is entitled to a priority date of September 7, 1998 based on the filing of GB9819420.2 filed on Sep. 7, 1998 in the United Kingdom; however, for the purpose of the instant examination, it is the filing of US application 60/103,670, filed October 9, 1998 that is the basis of the instant rejection, In re Hilmer, 359 F.2d 859, 149 USPQ 480 (CCPA 1966), that the effective date of a United States patent as a reference is not affected by the foreign filing date to which the patentee is entitled under 35 U.S.C. 119(a).

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Applicant argues that the Declaration under 37 USC 1.131 filed September 12, 2003 is sufficient to antedate U.S. Patent No: 6518399. This argument has been fully considered but not deemed persuasive. According to MPEP 715.02:

The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. In *re Tanczyn*, 347 F.2d 830, 146 USPQ 298 (CCPA 1965) (Where applicant claims an alloy comprising both nitrogen and molybdenum, an affidavit showing applicant made an alloy comprising nitrogen but not molybdenum is not sufficient under 37 CFR 1.131 to overcome a rejection under 35 U.S.C. 103 based on the combined teachings of one reference disclosing an alloy comprising nitrogen but not molybdenum and a second reference disclosing an alloy comprising molybdenum but not nitrogen). Note, however, where the differences between the claimed invention and the disclosure of the reference(s) are so small as to render the claims obvious over the reference(s), an affidavit or declaration under 37 CFR 1.131 is required to show no more than the reference shows. In *re Stryker*, 435 F.2d 1340, 168 USPQ 372 (CCPA 1971). In other words, where the examiner, in rejecting a claim under 35 U.S.C. 103, has treated a claim limitation as being an obvious feature or modification of the disclosure of the reference(s) relied upon, without citation of a reference which teaches such feature or modification, a 37 CFR 1.131 affidavit or declaration may be sufficient to overcome the rejection even if it does not show such feature or modification.

Further, a 37 CFR 1.131 affidavit is not insufficient merely because it does not show the identical disclosure of the reference(s) or the identical subject matter involved in the

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activity relied upon. If the affidavit contains facts showing a completion of the invention commensurate with the extent of the invention as claimed is shown in the reference or activity, the affidavit or declaration is sufficient, whether or not it is a showing of the identical disclosure of the reference or the identical subject matter involved in the activity. See *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Even if applicant's 37 CFR 1.131 affidavit is not fully commensurate with the rejected claim, the applicant can still overcome the rejection by showing that the differences between the claimed invention and the showing under 37 CFR 1.131 would have been obvious to one of ordinary skill in the art, in view of applicant's 37 CFR 1.131 evidence, prior to the effective date of the reference(s) or the activity. Such evidence is sufficient because applicant's possession of what is shown carries with it possession of variations and adaptations which would have been obvious, at the same time, to one of ordinary skill in the art. However, the affidavit or declaration showing must still establish possession of the invention (i.e., the basic inventive concept) and not just of what one reference (in a combination of applied references) happens to show, if that reference does not itself teach the basic inventive concept. In *re Spiller*, 500 F.2d 1170, 182 USPQ 614 (CCPA 1974) (Claimed invention was use of electrostatic forces to adhere dry starch particles to a wet paper web on the Fourdrinier wire of a paper-making machine. 37 CFR 1.131 affidavit established use of electrostatic forces to adhere starch particles to wet blotting paper moved over a fluidized bed of starch particles prior to the applied reference date. Affidavit was sufficient in view of prior art reference showing that deposition of dry coatings directly on wet webs on the Fourdrinier wire of a paper-making machine was well known in the art prior to the date of the applied reference. The

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affidavit established possession of the basic invention, i.e., use of electrostatic forces to adhere starch to wet paper.).

In the instant case, based on Applicant's Declaration (affidavit), it appears that Applicant was not in possession of the claimed assay system requiring a human GABA_BR2 prior to September 7, 1998; and nor is there any assertion that Applicant was in possession of such prior to the priority date of U.S. Patent No: 6518399 (October 8, 1998). Thus, the affidavit is not fully commensurate with the rejected claim and nor is it commensurate with the teachings of the prior art patent. Further, the omitted material, namely a human GABA_BR2, would not be considered obvious by one of ordinary skill in the art in view of the material supplied by the affidavit, nor could the teachings regarding a rat protein put one in possession of a human GABA_BR2, such protein being required by the instant claims and taught by U.S. Patent No: 6518399.

Applicant argues that the Declaration establishes that Applicants were in possession of an embodiment of the claimed invention before September 7, 1998. This argument has been fully considered but not deemed persuasive. The claims are directed to particular assays requiring particular proteins. The particular assay requiring a human GABA_BR2 was described in a US patent application before Applicants were in possession of this assay. Therefore, Applicant's claims to this assay are not patentable under 35 U.S.C. 102(e).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Please note the new official fax number below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (703) 306-5876. The examiner can normally be reached on Mondays through Thursdays from 8:00 a.m. to 5:30 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

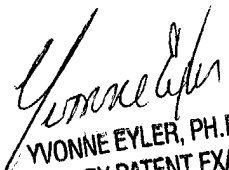
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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MB

A handwritten signature, possibly reading 'MB', in black ink.

December 4, 2003

A handwritten signature in black ink, appearing to read 'Yvonne Eyer'.

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600